MAR 0 7 2003

4. 510(k) Summary

Prepared December 13, 2002

TRADE NAME	Nautica™ Micro Catheter		
GENERIC NAME	Catheter, Continuous Flush		
CLASSIFICATION	Class II (21 CFR 870.1210) and Class II 21 CFR870.4450		
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618	CONTACT Regulatory Affairs (949) 837-3700	M
PREDICATE DEVICE(S)	MTI Titan™ Micro Catheter (K022003) MTI Rebar® Micro Catheter (K993672)		
DEVICE DESCRIPTION	The MTI Nautica™ Micro Catheter is an end-hole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated to increase lubricity.		
INDICATIONS FOR USE	The MTI Nautica™ Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media. Not intended for use in the coronary vasculature.		
TESTING	*In-vitro* performance testing of the MTI Nautica™ Micro Catheter included dimensional inspection, tensile strength tests, burst pressure tests, flow rate tests, torque tests and performance under simulated conditions. The biocompatibility of the MTI Nautica™ Micro Catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter was tested as an external communicating, blood contact, limited exposure (<24 hrs) device.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI Nautica™ Micro Catheter is substantially equivalent to the predicate devices in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Micro Therapeutics, Inc.
c/o Ms. Marilyn R. Pourazar
2 Goodyear
Irvine, CA 92618

Re: K024122
MTI Nautica™ Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continous Flush Catheter
Regulatory Class: Class II (two)
Product Code: 74 KRA
Dated: December 12, 2002
Received: December 16, 2002

Dear Ms. Marilyn:

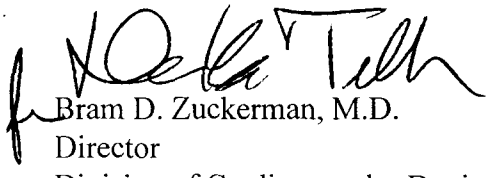
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

510(k) Number (if known): K024122

Device Name: MTI Nautica™ Micro Catheter

Indications for Use: The MTI Nautica™ Micro Catheter is intended to access peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media. Not intended for use in the coronary vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024122